for tobacco products to be altered in a way that makes them unacceptable to adult consumers, an illegal market to obtain such products will surely arise. This, ultimately, will be more harmful to the public health than if we never did anything at all. My bill leaves the authority to ban the use of tobacco products, or to eliminate nicotine completely from them, where that authority belongs: the Congress.

In addition, my bill allows for ''reduced-risk'' tobacco products. This is an area I believe could be very important in weaning existing tobacco users from more dangerous products—making it easier for them to quit, or at least giving them options that are less dangerous than the ones they are currently using.

I have sought to improve upon S. 190, which has been introduced in the other body. Like that bill, mine allows FDA to remove harmful substances from tobacco products, whether or not they are already on the market. It improves upon S. 190 by codifying the marketing and access restrictions found in the Master Settlement Agreement and the 1996 FDA regulation. These restrictions will go into effect shortly after enactment of the bill, and will subject them to federal enforcement. Furthermore, my bill directs FDA to regulate descriptors, such as ''light'' and ''ultralight'', and allows FDA to ban their use if they determine them to be misleading. I have also extended my bill to cover ''bidis'' and other tobacco products specifically directed towards children.

Mr. Speaker there are other important additions included in my bill, which are described in the attached section-by-section analysis. I urge your careful consideration of this extremely important legislation.

THE NATIONAL YOUTH SMOKING REDUCTION ACT

Section-by-Section Summary: The ''National Youth Smoking Reduction Act of 2001,'' among other things, creates a new chapter IX of the Federal Food, Drug, and Cosmetics Act (FDCA) to provide explicit authority to FDA to regulate tobacco products. The bill creates a separate chapter in the FDCA for tobacco products and thus expressly directs FDA to maintain a distinct regulatory program for tobacco products. The new FDCA chapter IX for tobacco products provides for comprehensive regulation of tobacco products.

The provisions of this new FDCA tobacco products chapter are based on the FDCA's device provisions, but some changes were made to make the provisions more appropriate for tobacco products. The most significant change is that the current statutory standard of ''reasonable assurance of safety and effectiveness,'' which is relied on when FDA makes a range of decisions for devices, was changed to ''appropriate for the protection of the public health,'' a standard which is more appropriate for tobacco products.

FDCA CHAPTER IX—TOBACCO PRODUCTS

Section 901—FDA authority over tobacco products

Clarifies that nothing in chapter IX shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products under the FDCA.

Also clarifies that chapter IX does not apply to tobacco leaf that is not in the possession of the manufacturer, or to producers of tobacco leaf; including tobacco growers, tobacco warehouses, and tobacco grower cooperatives.

Also clarifies that FDA employees may not enter onto a farm owned by a producer of tobacco leaf without the producer's written consent.

Section 902—Adulterated tobacco products, and Section 903—Misbranding tobacco products

Defines the conditions under which a tobacco product will be adulterated or misbranded under the FDCA, and subject to enforcement action. These provisions are similar to device law provisions, but are tailored to tobacco product regulation.

Section 903(b) authorizes the Secretary to require by regulation the prior approval of statements made on the label of a tobacco product, and explicitly states that no regulation issued under this subsection may require the prior approval by the Secretary of the content of any advertisement. This is similar to a device law provision.

Section 904—Submission of health information to the secretary

Within 6 months of enactment (and annually thereafter), each tobacco product manufacturer or importer must, among other document requirements, submit to FDA:

All documents relating to research activities, research findings, conducted, supported, or possessed by the manufacturer on tobacco or tobacco-related products;

All documents relating to research concerning the use of technology to reduce health risks associated with the use of tobacco; and

All documents relating to marketing research on tobacco products.

Section 905—Annual registration

Tobacco manufacturers are required to register each year with FDA in order to provide name and place of business information, as well as to provide lists of tobacco products manufactured by the establishment, and other information. Entities registered with FDA are subject to inspection every two years.

Section 906—General provisions respecting control of tobacco products

Provides authorities relating to the general regulation of tobacco products. This section includes protections for trade secret information similar to those for devices.

Under Section 906(d), the FDA through regulation may require that a tobacco product be restricted to sale or distribution upon such conditions, including restrictions on the access to, and the advertising and promotion of the tobacco product, if the Secretary determines that such regulation would be appropriate for the prevention of, or decrease in, the use of tobacco products by children under the age at which tobacco products may be legally purchased.

FDA may not require that the sale or distribution of a tobacco product be limited to prescription use only.

FDA is precluded from prohibiting tobacco product sales in face-to-face transactions by specific categories of retail outlets (for example, a ban on sales of cigarettes by gas stations).

Under Section 906(e), the FDA is authorized to promulgate regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, storage, and installation of a tobacco product conform to good manufacturing practice (GMPs) to assure that the public health is protected.

Prior to issuing GMP regulations, FDA is to consider recommendations from an advisory committee.

The bill makes explicit that the Secretary has the authority to grant either temporary or permanent exemptions or variances from a GMP requirement.

Section 907—Performance standards

FDA may promulgate performance standards for tobacco products if FDA determines that a standard is appropriate for protection of the public health. This authority is essentially the same as that for devices.

A decision as to whether a performance standard would be appropriate for the protection of the public health is to be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product.

Performance Standards must be promulgated through rulemaking, and interested persons may request that a proposed standard be referred by FDA to an advisory committee for recommendations on scientific issues.

Congress has the sole authority to approve any standard that eliminates all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or that reduces nicotine to zero. Also, no performance standard can render a tobacco product unacceptable for adult consumption.

Section 908—Notification and recall authority

Provides authority for FDA to order public notification if it determines that a tobacco product presents an unreasonable risk of substantial harm to public health, and such notification is necessary to eliminate that unreasonable risk. In addition:

FDA may issue cease and desist orders and order recalls of particular tobacco products where the Secretary finds that a tobacco product contains a manufacturing or other defect that is not ordinarily contained in tobacco products on the market and would cause serious, adverse health consequences or death.

The section's notification and recall provisions do not relieve any individual from liability under state or federal law.

Section 909—Records and reports on tobacco products

FDA may, by regulation, require a tobacco manufacturer or importer to report any information that suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected, adverse product experience.

Section 910—Premarket review of certain tobacco products

Provides for premarket review of new tobacco products that have the potential to increase the risks to consumers from conventional tobacco products being marketed at the time of the application.

Section 911—Judicial review

This provision provides judicial review procedures beyond the Administrative Procedure Act for FDA actions involving performance standards and premarket approval applications. This provision provides the same procedures as the parallel provision in device law.

Section 912—Reduced risk tobacco products

This section ensures that only those products designated by FDA as a ''Reduced Risk Tobacco Product'' may be marketed and labeled as such.

FDA may designate a product as a ''reduced risk tobacco product'' if it finds that ''the product is demonstrated to significantly reduce of harm to individuals caused by a tobacco product and is otherwise appropriate to protect the public health.''

A product designated as a ''reduced risk tobacco product'' is required to comply with certain marketing and labeling requirements. However, the FDA shall not prohibit communication that such product is a ''reduced risk tobacco product.''

FDA may revoke such designation after providing an opportunity for an informal hearing.